King, Valerie A.

From: Zedler, Barbara

Sent: Tuesday, August 05, 2003 5:21 PM

To: Adams, Candace R.; Feng, Shixia; Gogova, Maria; Jin, Yan; King, Valerie A.; Kinser, Robin D.; Liang, Qiwei; Mawyer, Denise T.; Mendes, Paul; Nelson, Bettie L; Oey, Jan; Roethig, Hans; Sarkar, Mohamadi; Unverdorben, Martin; Wang, Jingzhu

Subject: Clin Ops staff mtg 8/6

Importance: High

Sensitivity: Confidential

Dear All,

Attached are:

- the DRAFT TEMPLATE CSR (=clin study report) Vol 1 (=the 1st 100 or so pages of summary text including in-text tables, figs) which I drafted based on the 1st draft CSR for EHCJLI/01/02 which MDS prepared for us and which we reviewed last week,
- the actual 1st draft CSR for EHCJLI/01/02 with our comments and changes tracked in,
- recommendations for SOPs based on our cumulative experience w/ protocols and CSRs to date, that I believe are not or less controversial, and
- a list of "hot-button" (controversial) issues in our dept. on which it would be helpful to come to some consensus in order to move forward with standardizing our "output" (what we want to see in protocols and CSRs and how to get it).

I plan to review all at the staff mtg tomorrow in about 45 min., mainly to clarify going forward what we all (?most) agree on (and can be standardized to streamline our operations (SOPs)) and what are action items which need further input to resolve. So pls review especially the last 3 items above and come with your comments or suggestions. Thank you for all your input and help with this!!

Regards,
Barb

Barbara K. Zedler, M.D.
Director, Clinical Operations
Clinical Evaluation Group
RD&E/Philip Morris USA
Richmond, VA
barbara.k.zedler@pmusa.com
804.274.2799
cell 804.651.3544

PM3006736667

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